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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE:	:	
Fosamax Products Liability Litigation	:	1:06-md-1789 (JFK)
	:	
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<i>This Document Relates to:</i>	:	ANSWER AND AFFIRMATIVE
Mary Jane Pauling-Jones	:	DEFENSES OF MERCK
v. Merck & Co., Inc.	:	& CO., INC.;
	:	DEMAND FOR JURY TRIAL
Case No: 1:07-cv-6427-JFK	:	
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Defendant, Merck Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

1. Merck denies each and every allegation of Paragraph 1, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. Merck further admits that Plaintiff purports to bring a civil action for damages, but denies that there is any factual or legal basis for same.

I.

PARTIES

2. Merck states that it is without knowledge or information sufficient to form a belief as to the allegations in Paragraph 2.

3. Merck denies each and every allegation of Paragraph 3, except Merck admits that its principal place of business is located in Whitehouse Station, New Jersey

4. Merck denies each and every allegation of Paragraph 4, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information, and that FOSAMAX® is the brand name of alendronate sodium.

II.

JURISDICTION AND VENUE

5. The allegations contained in Paragraph 5 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in Paragraph 5, except that Merck admits for jurisdictional purposes only that the Plaintiff seeks in excess of \$75,000, and that Merck is without knowledge or information sufficient to form a belief as to Plaintiff's citizenship.

6. The allegations contained in Paragraph 6 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies the allegations of Paragraph 6.

7. Merck denies each and every allegation of the first clause of Paragraph 7. A response to the second clause of Paragraph 7 is not required.

III.

CONDITIONS PRECEDENT

8. Merck denies each and every allegation of Paragraph 8.

IV.

FACTUAL BACKGROUND

A. Fosamax Information

9. Merck denies each and every allegation of Paragraph 9, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck denies any allegations in Paragraph 9 inconsistent with that prescribing information.

10. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 10 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 10 with respect to Aredia and Zometa inconsistent with that prescribing information.

11. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 11 inconsistent with that prescribing information. Merck

respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia and Zometa and denies any allegations in Paragraph 11 with respect to Aredia and Zometa inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 11.

12. Merck denies each and every allegation of Paragraph 12, except that Merck admits that that Fosamax product sales in 2005 amounted to approximately \$3.19 billion.

B. Defendant's Failure to Warn of the Dangers of Fosamax

13. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the first sentence of Paragraph 13. Merck denies the remaining allegations in Paragraph 13, except that Merck refers the Court to the prescribing information for Aredia and Zometa and denies any allegations in the first clause of the second sentence of Paragraph 13 with respect to Aredia and Zometa inconsistent with that prescribing information.

14. Merck denies each and every allegation of Paragraph 14.

15. Merck denies each and every allegation of Paragraph 15.

16. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 16.

17. Merck denies each and every allegation of Paragraph 17.

18. Merck denies each and every allegation of Paragraph 18.

19. Merck denies each and every allegation of Paragraph 19.

20. Merck denies each and every allegation of Paragraph 20.

21. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 21, except that it admits that Ruggiero, et al., published an article entitled, "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004) and respectfully refers the Court to said article for its actual language and full text.

22. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.

24. Merck denies each and every allegation of Paragraph 24.

25. Merck denies each and every allegation of Paragraph 25.

26. Merck denies each and every allegation of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27.

C. Plaintiff's Use of Fosamax and Resulting Injury

28. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 28.

29. Merck denies each and every allegation of Paragraph 29.

30. Merck denies each and every allegation of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33.

V.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

34. Merck denies each and every allegation of Paragraph 34.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck denies each and every allegation of Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck denies each and every allegation of Paragraph 38.

VI.

CAUSES OF ACTION

Count I: Negligence

39. Merck repleads its answers to Paragraphs 1 through and including 38, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

40. The allegations in Paragraph 40 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

Count II: Strict Liability – Design Defect

44. Merck repleads its answers to Paragraphs 1 through and including 43, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

45. Merck denies each and every allegation of Paragraph 45.

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48.

49. Merck denies each and every allegation of Paragraph 49.

50. Merck denies each and every allegation of Paragraph 50.

Count III: Strict Liability – Failure to Warn

51. Merck repleads its answers to Paragraphs 1 through and including 50, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

52. Merck denies each and every allegation of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

Count IV: Breach of Express Warranty

54. Merck repleads its answers to Paragraphs 1 through and including 53, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

55. Merck denies each and every allegation of Paragraph 55, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a

prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

56. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

Count V: Breach of Implied Warranty

59. Merck repleads its answers to Paragraphs 1 through and including 58, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

60. Merck denies each and every allegation of Paragraph 60, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

61. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

Count VI: Deceptive Trade Practices

64. Merck repleads its answers to Paragraphs 1 through and including 63, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

65. Merck denies each and every allegation of Paragraph 65.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

Count VII: Fraudulent Misrepresentation

69. Merck repleads its answers to Paragraphs 1 through and including 68, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

70. Merck denies each and every allegation of Paragraph 70.

71. Merck denies each and every allegation of Paragraph 71.

72. Merck denies each and every allegation of Paragraph 72.

73. Merck denies each and every allegation of Paragraph 73.

74. Merck denies each and every allegation of Paragraph 74.

Count VIII: Negligent Misrepresentation

75. Merck repleads its answers to Paragraphs 1 through and including 74, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

76. Merck denies each and every allegation of Paragraph 76.

77. Merck denies each and every allegation of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

79. Merck denies each and every allegation of Paragraph 79.

80. Merck denies each and every allegation of Paragraph 80.

Count IX: Fraud and Deceit

81. Merck denies each and every allegation of Paragraph 81, except that Merck admits that it performed research and development work related to FOSAMAX®.

82. Merck denies each and every allegation of Paragraph 82.

83. Merck denies each and every allegation of Paragraph 83.

84. The allegations in Paragraph 84 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

85. Merck denies each and every allegation of Paragraph 85.

86. Merck denies each and every allegation of Paragraph 86.

87. Merck denies each and every allegation of Paragraph 87.

88. Merck denies each and every allegation of Paragraph 88.

89. Merck denies each and every allegation of Paragraph 89.

90. Merck denies each and every allegation of Paragraph 90.

91. Merck denies each and every allegation of Paragraph 91.

92. Merck denies each and every allegation of Paragraph 92.

93. Merck denies each and every allegation of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

98. Merck denies each and every allegation of Paragraph 98.

VII.

DAMAGES

A. Compensatory Damages

99. Merck repleads its answers to Paragraphs 1 through and including 98, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

100. Merck denies each and every allegation of Paragraph 100.

101. Merck denies each and every allegation of Paragraph 101.

102. Merck denies each and every allegation of Paragraph 102.

103. Merck denies each and every allegation of Paragraph 103, including subparts (a) through (f).

104. Merck denies each and every allegation of Paragraph 104, including subparts (a) through (f).

B. Punitive Damages

105. Merck repleads its answers to Paragraphs 1 through and including 104, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

106. Merck denies each and every allegation of Paragraph 106.

107. Merck denies each and every allegation of Paragraph 107.

108. Merck denies each and every allegation of Paragraph 108.

C. Treble Damages

109. Merck denies each and every allegation of Paragraph 109.

110. Merck denies each and every allegation of Paragraph 110.

VIII.

DEMAND FOR JURY TRIAL

111. The allegations of Paragraph 111 do not require a response.

IX.

PRAYER FOR RELIEF

Merck denies that Plaintiff is entitled to any of the relief requested in her Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were cause in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault and/or negligence.

NINTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions,

subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute

protected commercial speech under the applicable provisions of the United States and New York Constitutions.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff has not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claimed are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

FORTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

FORTY-THIRD AFFIRMATIVE DEFENSE

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

FORTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York
October 5, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: _____/s/
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